

Union List of Critical Medicines – first annual update (v2.1)

Presented by Siofradh McMahon on 30 September 2025

Supply and Availability of Medicines and Devices, Regulatory Science and Innovation Task Force (TRS-SAM)

Agenda

- Union List of Critical Medicines – objectives and scope
- Overview of the first Annual Update
- Next steps and actions required
- Future updates

Union List of Critical Medicines

- **Key aim:** To identify most critical medicines at Union level that are needed to ensure functioning of health care systems
 - Supply chains of critical medicines will be assessed for vulnerabilities with the aim to reduce the risk of shortages
- **Process used to develop the list:**
 - Medicines reviewed by all member states to determine criticality based on agreed methodology
 - Stakeholders requested to comment on criticality and suggest further medicines for review
 - Final review completed by member states before list finalised
- **Annual reviews foreseen**
 - Targeted review to capture medicines where criticality or availability may have changed (e.g. due to new market developments, critical shortages, changes in indication etc)



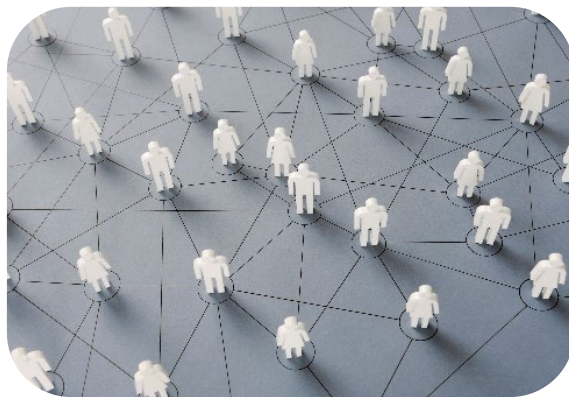
Objectives and scope – How is the list used?



Availability

Ensure critical medicines for EU health systems are always available.

- Enable short- to medium/ long-term supply security measures.



Regulatory actions

EMA/EMRN monitor medicines on the list to minimise supply disruptions.

- Measures leverage existing processes/ structures defined by EMA's SPOC Working Party and MSSG (based on existing toolkits)



Industrial capacity/support

Industrial and structural policy recommendations for critical medicines e.g. supplier diversification, re-shoring, investment incentives, procurement agreements tied to contractual obligations for supply

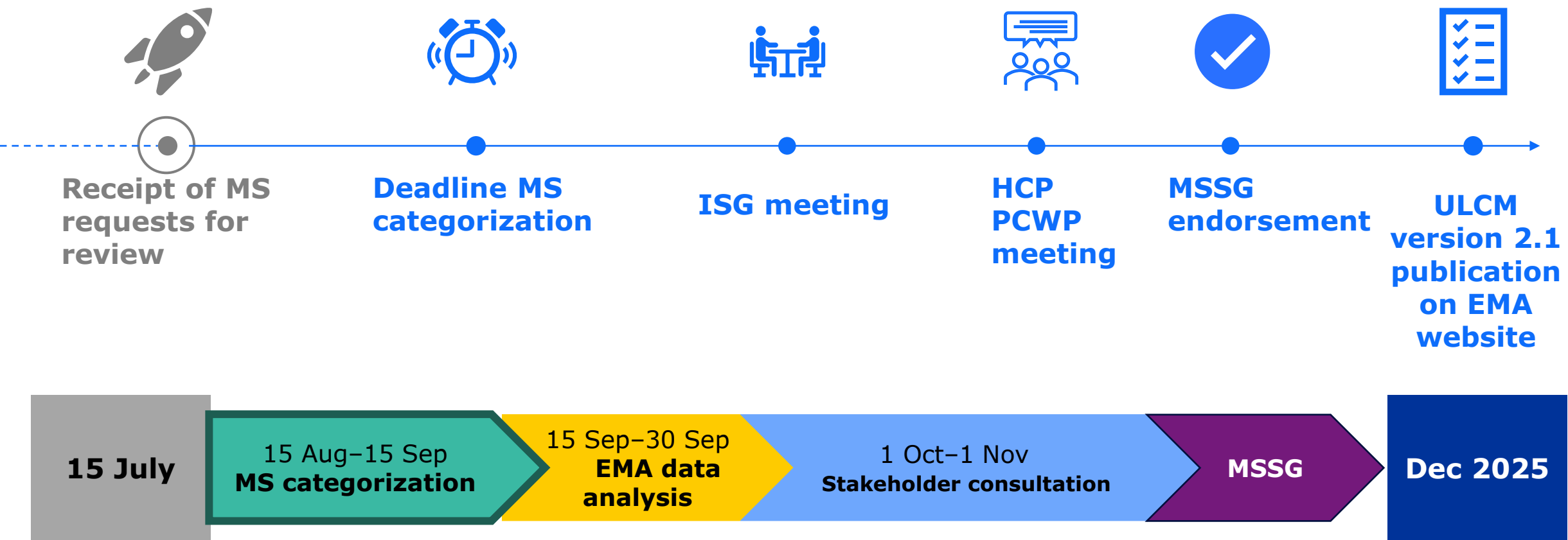


Policy/legislation

Planned: The proposed EU pharma legislation revision will define additional obligations for MAHs and Member State NCAs.

Future: The Critical Medicines Act is a key priority of the Commission's mandate (complements new pharma legislation revision with industrial policy measures).

Timeline: 2025 annual update



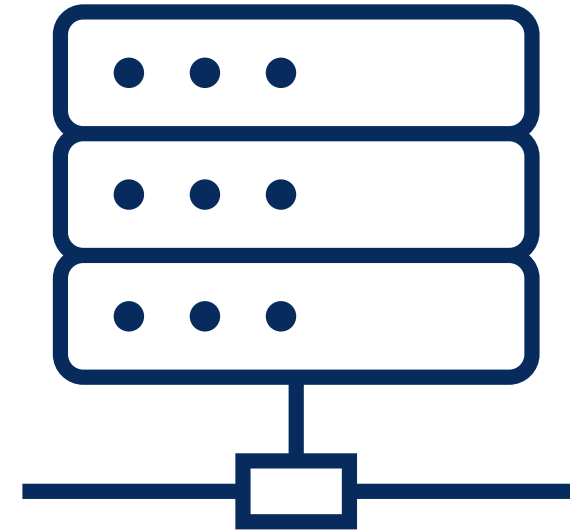
Annual update 2025: in-scope medicines

- **61 Active Substance Groups** being assessed
 - Corresponds to approximately **11k authorised medicinal products** from Article 57 database of authorised medicinal products in the Union
- Active substance groups for consideration were **proposed by member states** based on the following criteria:
 - History of critical shortages with potential criticality based on lack of available alternatives
 - New market developments **increasing** demand/criticality for particular medicine
 - New market developments **decreasing** demand/criticality for particular medicine
 - Change in indication of the authorised medicine that **increases or decreases** the previously assessed criticality

Annual updates: reminder of threshold for criticality

Reminder of prerequisites to be met (at the level of pharmaceutical form):

- Data driven threshold
 - Ensure inclusion of medicines critical at **union level**
- Absolute numbers — taking into account all MSs
 - At least 15 countries rated the pharmaceutical form as critical
- Relative numbers — taking into account the MSs where the product is marketed
 - More than two-thirds (67%) of the MSs, where the pharmaceutical form is marketed, assessed it as critical



Next steps and actions for annual review 2025



Call for input will be circulated to stakeholders early October 2025

4 weeks to respond



Request to perform targeted review of outcome of member state criticality assessment

Full list of active substance groups considered will be shared, along with the outcome of the member state review highlighting which active substance groups are expected to be included in the next version of the union list



No new active substance groups to be considered at this time

Future call for input planned in January 2026 for suggestions of medicines to be considered for inclusion/removal in future annual updates

Planning for future annual reviews is underway

- Request for input to be circulated to stakeholders and member states in parallel January 2026
 - Active substances to be considered for inclusion and for removal
- EMA review of data and request for member state categorisation planned for Q2 2026
- Input from stakeholders to be requested Q3 2026
- Publication of updated list targeted Q4 2026





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